PD4 Exh 8

CardinalHealth

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PROCESS TO ESTABLISH SOM THRESHOLD LIMITS	12/22/08	HSCSQRA-CAD-C002	
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1.0 PURPOSE

To outline the conceptual framework and methodology to follow when formulating threshold limits for the Suspicious Order Monitoring (SOM) program.

2.0 SCOPE

All HSCS Pharmaceutical Operations and Customers, Quality and Regulatory Affairs, Supply Chain Integrity

3.0 INCLUDED ATTACHMENTS AND FORMS

None

4.0 POLICY

The intent of calculating threshold limits is to establish a baseline purchase pattern for all monitored items. The baseline purchase pattern is then adjusted up by a statistically significant factor or variable to formulate the threshold limit. The subsequent implementation of threshold limits allows a SOM program to identify customers whose order pattern significantly deviates from the baseline or normalized purchase pattern.

Threshold limits are to be determined for all monitored items sold by, and all customers serviced by, each Business Unit. Monitored items include all controlled substances, List 1 chemicals, and state monitored items available for distribution within each Business Unit. A customer is defined as a unique DEA Registrant which has the ability to purchase a monitored item.

4.1 Definitions

DEA Registrant	A customer that is licensed by the DEA and that has the ability to purchase a monitored item.
Monitored Item	Includes any controlled substances, List 1 chemicals, or state monitored items. All monitored items are to be included within the SOM Program.
Segment	A classification system used to identify like DEA registrants. Segmenting customers allows for granularity when assessing purchase patterns and allows for the establishment of more precise threshold limits.
Drug Family	A series of associated controlled substances grouped together by the underlying chemical ingredient. Each monitored item is included within one drug family.
Base Code	The four digit value associated with each drug family.
Dosage Unit	A standardized measure of the quantity of doses per the sale unit of a controlled substance.
Threshold Limit	A value assigned by Quality & Regulatory Affairs that limits the quantity (dosage units) of monitored items within each drug family a customer may purchase.

4.2 Methodology

The following methodology outlines the steps to be followed when calculating threshold limits. Any variation or deviation from the below methodology must be approved by Corporate QRA.

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4.2.1 Extract and format list of customers and historical sales data.

a. Complete a unique customer roster containing each DEA Registrant that has purchased a monitored item, as well as a column indicating whether or not the customer is currently "active." "Active" is defined as having the ability to purchase a monitored item at the time of the data extract.

b. Compile all historical sales for all monitored items for all customers over the most recent 12 month time period. The 12 month time period should be based on the date the product was shipped.

c. Identify the number of monitored item drug families sold to the DEA Registrant. Threshold limits are to be calculated for each Base Code, or drug family, sold to each DEA Registrant.

4.2.2 Differentiate customers through segmentation. The segmentation of customers is preferred, but is an optional step.

a. Segmentation within the customers may occur by size or specialty, or a combination of both.

i. Any segmentation based on size must be based on the total quantity of monitored item dosage units purchased over a specified time period.

ii. Any segmentation done by specialty is to be based on DEA Activity Code. The DEA Activity Code is an alpha character assigned by the DEA to each DEA Registrant to identify the type of business category the Registrant is engaged in.

b. The segments must be tested prior to proceeding to the next step to ensure that an adequate sample size exists. The testing should encompass the following:

i. Review the total number of DEA Numbers within each segment to ensure that the segment contains at least 5% of all customers;

ii. Review the number of drug families purchased by customers within each segment to ensure that at least 50% of the drug families were purchased by at least 10% of the customers within the segment.

4.2.3 Evaluate historical controlled substance sales data per drug family, per month for each customer segment to establish appropriate threshold limits.

a. All historical invoice level purchases for all monitored items are to be aggregated by DEA Number, Base Code, and dosage units purchased per month.

b. Calculate threshold limits for each Base Code for all Customer

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segments.

i. Threshold limits are to be calculated using consistent historical sales data. The intent is to remove erratic purchase patterns from the data as to not skew the threshold limit values.

ii. Determine the total dosage unit quantities purchased by segment per Base Code over the 12 month period.

iii. Identify the number of DEA Numbers who purchased each Base Code over the 12 month period for each segment.

iv. Determine the annual quantity per DEA Number for each Base Code for each segment.

v. Determine the monthly quantity per DEA Number per Base Code for each segment.

vi. Multiply the monthly quantity per DEA Number per Base Code for each segment by a factor of 3, 5, or 8. The multiplication factor of 3, 5, or 8 is to be implemented in the following manner:

- Three Factor : Hydrocodone, Oxycodone, Alprazolam, and Phentermine drug families;
- Five Factor : All remaining ARCOS reportable drug families;
- Eight Factor : All remaining monitored items not multiplied by a factor of three of five.

vii. To utilize a threshold calculated in this step, historical data from at least 3% of all customers included within the segment (with no less than 5 customers) must be utilized. For example, if the customer segment encompasses 100 customers, at least 3 customers must have consistent historical sales data in order to establish a threshold limit for the entire segment. This step ensures that a threshold limit for an entire segment is not based on the historical purchase pattern of one or two customers.

c. Conduct a gap threshold limit analysis. In the event that an adequate sample does not exist to formulate a threshold limit for a Base Code, initial threshold limits established for the segment by Deloitte will be used as a baseline. Any gap analysis is to be approved by the Manager and Vice President.

4.2.4 Incorporate KYC information to establish final threshold limits.

a. Adjustments can be made to the threshold limits based on background information, or “Know Your Customer” (KYC) documentation. The intent

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of this step is to adjust threshold limits based on the associated level of risk.

i. An example of this step would include increasing a customer's threshold limits by a % if the customer has a documented diversion or loss prevention program. In essence, Cardinal's role in the customer's anti-diversion decreases as the customer ability increases.

4.2.5 Apply rounding logic and finalize threshold limits.

a. Rounding logic is to be applied to finalize threshold limits. The rounding logic will vary by drug family and will be based on the standard package size sold.

i. An example of this step would be rounding a threshold limit (i.e. threshold value of 4,775) up to the nearest 500 because the standard package size is in increments of 500.

4.3 Conclusions All threshold limits are to be reviewed and approved by the Vice President of Anti-Diversion.

5.0 APPLICABLE DOCUMENTS None

Approvals on file in Healthcare Supply Chain Services (Transportation and Warehouse) Document Center	
Approvers:	Owner: Doc Center: Jason Paul Snouffer

Change History		
DCN-2278	12/22/08	Initial release of new procedure, HSCSQRA-CAD-C002.